

## IN THE UNITED STATES PATENT & TRADEMARK OFFICE

**Applicant** 

David J. Grainger

Serial. No

09/754,775

Examiner: Kim, Jennifer M.

Filed

January 4, 2001

Group Art Unit: 1617

For

PREVENTION AND TREATMENT OF CARDIOVASCULAR

PATHOLOGIES WITH TAMOXIFEN ANALOGUES

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

## **CERTIFICATE OF MAILING**

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-

February 13, 2006

Date of Deposit

Van H. Nguyen

Attorney Name

Signature

<u>56,5</u>71

PTO Registration No.

February 13, 2006

Date of Signature

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed infra and on the attached PTO 1449 and respectfully requests that the listed documents be considered by the Examiner and made of record in the above-captioned application.

NY02:540282.1 -1-

- 1 Wärri, Anni, Toremifene-Induced Regression in Breast Cancer, 1993, pp. 1-76 plus references I-V.
- Wärri, Anni and Harkonen, P., Indirect Regulation Of erbB2 Expression by Antiestrogen in Human Breast Cancer Cells, 1993, pp. 1-12.
- Wärri, Anni, Isola, Harkonen, Estrogen and antiestrogen regulation of amplified erbB2 gene expression and ectodomain shedding in BT-474 human breast cancer cells, 1993, pp. 1-24.
- Wärri, Anni et al., Apoptosis in toremifene-induced growth inhibition of human breast cancer cells in vivo and in vitro, J Natl Cancer Inst. 1993 Sep 1;85(17):1412-8.
- 5 Sawada et al., Fifty-Two Week Oral Toxicity Study and Recovery Study of Toremifene Citrate (NK622) in Female Rats, 1992, Pharmacometrics [Oyo yakuri], Vol. 44, pp. 357-373. (with translation from Japanese pp. 1-16)
- Wärri AM, Laine AM, Majasuo KE, Alitalo KK, Estrogen suppression of erbB2 expression is associated with increased growth rate of ZR-75-1 human breast cancer cells in vitro and in nude mice. Int J Cancer. 1991 Oct 21;49(4):616-23.
- 7 Vuorio T, Warri A, Sandberg M, Alitalo K, Vuorio E. Expression of the c-Ha-ras and neu oncogenes in DMBA-induced, anti-estrogen-treated rat mammary tumors. Int J Cancer. 1988 Nov 15;42(5):774-9.

This Information Disclosure Statement is being filed in response to the office action mailed on August 11, 2005, and lists the full Wärri thesis, attached references I-V of Wärri, copies of the original and an English translation of the Sawada reference, of which the abstract of Wärri and the Japanese language copy of Sawada were listed in the Examiner's form 892. Therefore, applicant does not believe that any fee is due in connection with the submission of this paper.

Copies of the listed documents are attached.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents

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Attorney's Docket 074973.0117
PATENT

are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited document(s) do not constitute "prior art" under United States law, applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Applicant does not believe that any fee is required in connection with the submission of this document. However, should any fee be required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. Duplicate copies of this sheet are enclosed.

Respectfully submitted,

BAKER BOTTS L.L.P.

Lisa B. Kole

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Van H. Nguyen

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Form PTO-1449 U.S. Department of Commerce	Atty. Docket No.	Serial No.
(REV. 2-82) Patent and Trademark Office	074973.0117	09/754,775
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant David J. Grainger	
(Use several sheets if	Filing Date	Group
(Use several sheets if necessary)	January 4, 2001	1617
FFR 16 2006 \$	Examiner Kim, Jennifer M.	
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U.S. PATENT DOCUMENTS								
*Exam. Initial.	No.		Document No.	Date	Name	Class	Subclass	Filing Date if Approximate.

FOREIGN PATENT DOCUMENTS							
Exam Initial	No.	Document No.	Date	Country	Class	Subclass	Translation Yes No
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Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	1	Wärri, Anni, Toremifene-Induced Regression in Breast Cancer, 1993, pp. 1-76 and references I-V.
	2	Wärri, Anni and Harkonen, P., Indirect Regulation Of erbB2 Expression by Antiestrogen in Human Breast Cancer Cells, 1993, pp. 1-12.
	3	Wärri, Anni, Isola, Harkonen, Estrogen and antiestrogen regulation of amplified erbB2 gene expression and ectodomain shedding in BT-474 human breast cancer cells, 1993, pp. 1-24.
	4	Wärri, Anni et al., Apoptosis in toremifene-induced growth inhibition of human breast cancer cells in vivo and in vitro, J Natl Cancer Inst. 1993 Sep 1;85(17):1412-8.

NY02:540270.1	
Examiner	Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. 074973.0117	Serial No. 09/754,775
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Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	5	Sawada et al., Fifty-Two Week Oral Toxicity Study and Recovery Study of Toremifene Citrate (NK622) in Female Rats, 1992, Pharmacometrics [Oyo yakuri], Vol. 44, pp. 357-373. (with translation from Japanese pp. 1-16)
	6	Wärri AM, Laine AM, Majasuo KE, Alitalo KK, Estrogen suppression of erbB2 expression is associated with increased growth rate of ZR-75-1 human breast cancer cells in vitro and in nude mice. Int J Cancer. 1991 Oct 21;49(4):616-23.
	7	Vuorio T, Warri A, Sandberg M, Alitalo K, Vuorio E. Expression of the c-Ha-ras and neu oncogenes in DMBA-induced, anti-estrogen-treated rat mammary tumors. Int J Cancer. 1988 Nov 15;42(5):774-9.

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